12-10-2015

200.01 -- Human Subject Research and the Concordia University Institutional Research Board

CONCORDIA UNIVERSITY
-PORTLAND, OREGON-

Official University Policy

Title: Human Subject Research and the Concordia University Institutional Review Board

Constituents: University Faculty, Staff, and Students and External Investigators seeking University collaboration in human research

CATEGORY	Requested Implementation Date: December 1, 2015 Approval Date: *December 10, 2015*	POLICY NUMBER
ACADEMICS AND RESEARCH (200)		**200.01**

POLICY STATEMENT

General Responsibility and Statement of Principles

Federal and state laws mandate that institutions have an institutional review board (IRB) to review and approve human subjects research before it can begin. The IRB Office must interview individuals in the institution to deem what research needs a complete IRB Application review. The institution must provide resources to support the IRB and the activities of identifying and reviewing research, as described in the Federal Regulations Common Rule 45 CFR 46. Each member of the University community engaging in human subjects research and external investigators seeking University collaboration in human research shall adhere to all federal, state and local laws and Concordia University – Portland rules, regulations and policies, pertaining to the security and protection of human subjects in research.

These federal and state laws were guided by principles developed in the 1979 report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research, which is now called "The Belmont Report." Three major ethical principles are employed in the review process to protect human subjects: Respect for Persons, Beneficence, and Justice. Concordia University adopts these three key ethical principles as well as our ethical principles as a Christian University.

Human subjects research

Research is defined as investigations or systematic study, summary, or comparison conducted with the intent to gain or promote generalizable knowledge. Although the intent to publish or present a

seminar is not the unique definition of generalizable knowledge, it is a good indicator. For research to be considered human subjects research, it must involve

- Human interactions with alive individuals (observing, testing, tabulating, and/or recording even if this is via remote data collection) and
- Any information that any reasonable person would consider private (including their deciding to be in the study and/or their unknowingly providing private information linked to other data).

Requirements to conduct human subjects research

The Concordia University – Portland IRB (CUP IRB) has a role that touches every individual at CU-Portland. The university-wide role and authority of the CUP IRB is to oversee the following:

- Educating on human subjects research, human protections and research integrity;
- Screening of research for exempt status: in some cases (but not all cases) the following might be exempt from a complete IRB Application for review as mandated by the Federal Regulations Common Rule.
    - Exempt when only using publically available data that is not private information
    - Exempt when classroom or class-based research that will not be published, and
    - Exempt when institutional service or assessment surveys that will not be published;
- Reviewing and approving, requiring modifications, or not approving non-exempt research. Non-exempt research reviews are decided by a committee. The committee includes volunteers with varying perspectives and experiences as faculty, researchers, nonscientists, students, and non-University/external community members.

In specific situations, other federal and state laws and university procedures and policies may apply. For example, research that asks sensitive questions and/or involves minors will never be exempt from having some IRB review. As another example, the CUP IRB will refer anyone planning a survey that involves the CU community as a group: e.g.; using email that is “all Students,” “all Faculty,” and/or “all Staff,” to the Office of Institutional Research and Effectiveness (IRE), since the Office of IRE must review and give permission for any research or survey using this CU community group email.

Concordia University cannot approve research that is disapproved by the CUP IRB; however, Concordia University can disapprove research even if the research was approved by the by CUP IRB.

Researcher (Faculty, Students, Staff, and Extramural Associates) Responsibilities

- Researchers must describe their research plans to the CUP IRB when planning human subject research or when there is a question on whether or not the research is exempt.

- Human subjects researchers must follow the procedures for submitting an IRB application, waiting for CUP IRB approval before conducting human subject research, and completing reporting procedures as described on the IRB website: www.cu-portland.edu/irb.
- Human subjects researchers must meet all Federal Regulations Federal Regulations Common Rule 45 CFR 46 and must take governmental-approved human subjects protection training (see www.CITIprogram.org) that describes the researcher's responsibilities and the requirement for the CUP IRB.

All Faculty, Students, Staff, or Extramural Associate collaborating with Concordia University involved in research (whether or not this is classified as Human Subjects Research), must do the following:

- Comply with the reporting, verifying, and auditing requirements of the CUP IRB.
- Follow instructions of the CUP IRB when the CUP IRB refers the researcher(s) to another Policy or Office, regardless of approval by the CUP IRB, to ensure applicable clearances before the research begins.
- Follow standards for ensuring, at least, the minimum requirements for data security and privacy.
- Conduct research in an ethical manner, working with integrity in the design, execution, data protection, and publication of research.
- Interact with individuals being recruited or participating in any survey or research involving Concordia University in an ethical and principled manner.

Enforcement

Persons who fail to adhere to this Policy may be subject to penalties as provided by law and/or disciplinary action, including dismissal or expulsion. Violations will be handled through the University disciplinary policies applicable to employees and students. The University may also refer suspected violations of applicable law to appropriate law enforcement agencies.

REASON FOR POLICY

To establish guidelines for ethical and compliant use of human subjects in research.

RELATED INFORMATION

Federal Laws include the following:

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Common Rule 45 CFR 46: Protection of Human Subjects 45 CFR Part 46 §§ 46.101-46.124
Electronic Communications Privacy Act of 1986 (ECPA), 18 U.S.C. § 2510-22.
Family Educational Rights and Privacy Act, 20 U.S.C. § 1232g; 34 CFR Part 99 ("FERPA" also known as the "Buckley Amendment")
The Federal Privacy Act of 1974 as it relates to educational institutions receiving federal funding
Health Insurance Portability and Accountability Act, Administrative Simplification Provisions, 42 U.S.C. § 1320d, et seq. ("HIPAA")
HIPAA Privacy Rule, 45 CFR Part 160; 45 CFR Part 164, Subparts A and E
HIPAA Security Rule, 45 CFR Part 164, Subpart C
No Child Left Behind Elementary and Secondary Education Act (ESEA)
HHS 42 CFR Part 93 Public Health Service Policies on Research Misconduct
NSF 45 CFR Part 689 National Science Foundation, Research Misconduct § 689.2
Secretary of Education Student Rights in Research and Testing 34 CFR PART 98
US Food and Drug Administration 21 CFR 50

State Laws include the following:

Oregon General Law
Oregon Research and Privacy Protection Law (ORS 419, 432, and 444)
Oregon Genetic Privacy law (ORS 333-025-0100- 333-025-0120)
Oregon Reporting and Confidentiality Law (ORS 409.273 - ORS 409.292)
Idaho General Law
Idaho Genetic Testing Privacy Act (Idaho Statutes 39-8301)
Idaho Education Privacy Statues (Idaho Statutes 33-133)

Other CU Policies include the following:
CU-Portland Information Technology (IT) Data Security Policies
CU-Portland Office of Institutional Research and Effectiveness Policies

RESPONSIBLE UNIVERSITY DEPARTMENT / OFFICE

Office of Provost, Director of IRB
Concordia University – Portland
2811 NE Holman Street
Portland, OR 97221

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FORMS / ONLINE PROCESSES

The CUP IRB process is described at www.cu-portland.edu/irb with forms available at www.cu-portland.edu/forms. More information is available upon request at irb@cu-portland.edu.